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UNCLAS SECTION 01 OF 02 WARSAW 000308

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SENSITIVE

STATE FOR EUR/NCE/MSESSUMS
STATE PASS USTR FOR DONNELLY/ERRION/WEISEL
COMMERCE FOR 4232/ITA/MAC/EUR/OECA/MROGERS

REF: (A) Warsaw 0068 (B) Warsaw 0280

E.O. 12958: N/A
TAGS: ETRD KIPR PL
SUBJECT: POLAND: Comment on Pharma's Special 301 Input

Summary

¶1. (U) Sensitive but unclassified. Not for distribution outside USG.

¶2. (SBU) Pharma's call for Priority Foreign Country (PFC) status for Poland is understandable. The industry has indeed faced many challenges in dealing with the Polish government prior to accession, and some of these issues have exacerbated dealing with the Ministry of Health in the post-accession environment as well. However, the industry's main problem, which has consistently been at the foundation of most, if not all, its complaints, has been access to the reimbursement list. And while issues relating to inadequate IPR protection played a role in hindering the competitiveness of the industry in the late 1990s, data exclusivity problems do not appear, given the evidence submitted, to be the main culprit in limiting industry's effectiveness. Indeed, we have proposed a strategy (reftel A) for dealing with the new government that is already bearing fruit, thanks in great measure to the visit Commerce Secretary Gutierrez. In sum, we believe that cooperative

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engagement is the best way to address industry's main complaint: access for innovative drugs to the reimbursement list. End Summary.

Industry's Points: Data Exclusivity

¶3. (SBU) As we review industry's submission, we find a number of complaints, some with more substantive merit than others. But most of the complaints are the same that we have read in previous years' submissions. This does not mean the problems should be discounted. However, it does beg the question for this year's review as to what specific 301-related issues the industry has. We have discussed this very issue with the primary AmCham pharmaceutical group (LAWG) as well as with specific companies. We emphasized the need for current actionable examples regarding violations of data exclusivity.

¶4. (SBU) We did get a number of complaints regarding "ghost list" drugs and the increasing number of molecules found on that list (reftel B), but by industry's admission, some of these drugs do not even exist as a marketable product. Even the example of Fozomax, which industry uses in its submission as evidence of the data exclusivity problem, is not actionable on that basis. We asked Merck (protect) directly if the company could claim the generics competing with Fozomax violated its patent (as reported in reftel A). The answer was no. As to Lilly's Zyprexa, we understand this drug was subject to IP-related judicial proceedings in the United States as well. Again, this does not diminish the threat to industry that Poland's lack of commitment to cooperation with the innovative drug industry demonstrates. But it does underscore why it is difficult for the Embassy to raise data exclusivity violations as a cudgel to gain access to the reimbursement list for innovative drugs, and why enhancing cooperation and dialogue is far more likely than threatening sanctions to get industry what it wants.

¶5. (SBU) It is true that Poland has not implemented fully all data exclusivity directives (65/65 is still pending implementation). But Poland has filed for an exception to implementation for full term data exclusivity in accordance with EU rules. From our perspective, it is difficult to view this request as substantive IPR violation.

Industry's Points: Customs and Margins

¶6. (SBU) Industry has been rightly concerned about this issue, as the potential damage could be catastrophic, with literally hundreds of millions of dollars in financial penalties at stake. However, the issue has been winding its way through the Polish courts, which have been consistently rendering decisions in industry's favour. And while the case is still in court, the Minister of Health himself is pressing U.S. officials and industry to look for a settlement "out of court." Previously, industry had been eager to pursue this approach as well. Now, it smells blood, and an out of court settlement appears unlikely. We support industry's position on the substance of the issue. As to the tactics related to resolving it, we of course defer to the LAWG. However, given that the case is being handled without any undue political interference, we believe the issue does not rise to the level that would warrant an elevation of Poland's watch list status.

Give Dialogue a Chance

¶7. (SBU) Perhaps the most compelling reason to avert raising Poland's status is the fact that we now are dealing with a new government, which in meetings with Embassy officials and Washington visitors has impressed us with its desire to engage with us and industry to resolve problems on the IPR front. In discussions with Secretary Gutierrez, Minister Religa gave reassuring answers to the Secretary's points about innovative drug access to the reimbursement list (again this is *the* major issue for industry). Religa, a medical doctor and not a PiS party member, appeared genuine when he expressed both his desire to add innovative drugs to the reimbursement list and difficulties in dealing with the Finance Ministry to obtain the necessary budget to do it. While words and deeds, of course, need to be brought into synch, we nonetheless believe it is important to give substantive engagement a chance. As reported, we are currently working to establish a regular dialogue between industry and the Health Ministry that we hope will resolve the thorniest outstanding issues. It would send the wrong message to this Polish government if we were to use the stick as our opening gambit.